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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,426	12/30/2003	David J. Hansen	20020605.ORI	8112

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 02/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/748,426

Applicant(s)

HANSEN ET AL.

Examiner

Michael Kahelin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☒ Claim(s) 1 and 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 04022004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities:
"submuscellarly" should read "submuscularly" on page 1, line 13; and there is an incomplete sentence on page 5, line 11.

Appropriate correction is required.

Claim Objections

2. Claims 1 and 13 are objected to because of the following informalities: in claim 1, line 20, "posts" should read "ports"; and in claim 13, line 12, "then" should read "the".
Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3, 4, 7, 10, 11, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Frey et al. (US 4,860,750 hereinafter "Frey").
5. In regards to claims 1 and 7, Frey discloses an implantable pulse generator (10), a device connector with a longitudinally extending bore (14), an electrical contact

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disposed within the connector (18) to cooperate with a conductive pin (25 and 24), a first and second side port in general alignment with the contact (Fig. 3), an elastomeric tube in the first or second side port (26 and col. 4, line 60), a first latch member adapted for insertion into the first port and having bifurcated legs (Fig. 4), and a second latch member (38) that is inserted through the second side port to spread the bifurcated legs and press the elastomeric tube (26) against the conductive pin (25 and 24) to hold the pin in place against the contact (18). Please note that examiner is interpreting the "pin" to comprise both elements 25 and 24 and that element (e) is a product-by-process limitation. Therefore, the only consideration given patentable weight is the structural limitation of an elastomeric tube in the first or second side ports, with no consideration given to how it got there.

6. In regards to claims 3 and 10, the first latch member comprises a flat head (45) with integral legs extending perpendicularly (40a and 40b).

7. In regards to claims 4 and 11, the second latch member comprises a flat head (unlabelled surface at far right of element 38 in figure 4a) and an integral tapered wedge extending perpendicularly (43).

8. In regards to claim 14, the contact, first latch, and second latch cooperate with a predetermined portion of the conductive pin (portion shown in element 18), defined by an international standard for medical leads (col. 4, line 65). Examiner is interpreting "unipolar" as an international standard.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 2, 5, 9, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frey in view of Rowley et al. (US 6,080,188 hereinafter "Rowley"). Frey discloses the essential features of the claimed invention including barbs (41a and 41b) on the bifurcated legs and shoulders (42a and 42b) in the insertion tube (30), interlocking first and second latches (Fig. 5). Frey does not disclose that the insertion tube, transverse to the conductive pin, is elastomeric. Rowley teaches of providing an elastomeric tube for applying a tool-less frictional fixation means to a medical lead to avoid rough contact with the lead body, while still providing the contact force necessary to fix the lead in place. Therefore, it would have been obvious to one having ordinary

skill in the art at the time the invention was made to provide Frey's invention with an insertion tube (30) made of an elastomer for applying a tool-less frictional fixation means to a medical lead to avoid rough contact with the lead body, while still providing the contact force necessary to fix the lead in place.

12. Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frey in view of Bradshaw (US 5,486,202 hereinafter "Bradshaw"). Frey discloses the essential features of the claimed invention except for an elastomeric tube that provides a fluid impervious seal when latched. Bradshaw teaches of providing an elastomeric seal (40) that provides a fluid impervious seal when latched to disrupt electrical continuity between the contact and the body fluid. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Frey's invention with an elastomeric seal that provides a fluid impervious seal when latched to disrupt electrical continuity between the contact and the body fluid.

13. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Frey in view of Rowley as applied to claim 12 above, and further in view of Bradshaw. The modified invention of Frey discloses the essential features of the claimed invention except for an elastomeric tube with flanges that provide a fluid impervious seal when latched. Bradshaw teaches of providing an elastomeric flange (40) that provides a fluid impervious seal when latched to disrupt electrical continuity between the contact and the body fluid. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Frey's invention with an elastomeric

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flange that provides a fluid impervious seal when latched to disrupt electrical continuity between the contact and the body fluid.


Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Another example of a tool-less latching means is provided.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


GEORGE R. EVANISKO
PRIMARY EXAMINER
1/26/6

MWK

